Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,

Complainant

v.

A I Traders, LLC / Aswad Janoo, d/b/a Choice Tobacco,

Respondent.

Docket No. C-15-49 FDA Docket No. FDA-2014-H-1543

Decision No. CR3520

Date: December 17, 2014

INITIAL DECISION AND DEFAULT JUDGMENT

The Center for Tobacco Products (CTP) filed an Administrative Complaint (Complaint) against Respondent, A I Traders, LLC / Aswad Janoo, d/b/a Choice Tobacco that alleges facts and legal authority sufficient to justify the imposition of a civil money penalty of \$500. Respondent did not answer the Complaint, nor did Respondent request an extension of time within which to file an answer. Therefore, I enter a default judgment against Respondent and assess a civil money penalty of \$500.

CTP began this case by serving the Complaint on Respondent and filing a copy of the Complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The Complaint alleges that Respondent impermissibly sold flavored cigarettes, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, Cigarettes and Smokeless Tobacco, 21 C.F.R. pt. 1140 (2013). CTP seeks a civil money penalty of \$500.

On October 16, 2014, CTP served the Complaint on Respondent by United Parcel Service, pursuant to 21 C.F.R. §§ 17.5 and 17.7. In the Complaint and accompanying cover letter, CTP explained that within 30 days, Respondent should pay the proposed penalty, file an answer, or request an extension of time within which to file an answer. CTP warned Respondent that if it failed to take one of these actions within 30 days, an Administrative Law Judge could, pursuant to 21 C.F.R. § 17.11, issue an initial decision ordering Respondent to pay the full amount of the proposed penalty.

Respondent has not filed an answer within the time provided by regulation, nor has it requested an extension. Pursuant to 21 C.F.R. § 17.11(a), I am required to "assume the facts alleged in the [C]omplaint to be true" and, if those facts establish liability under the Act, issue a default judgment and impose a civil money penalty. Accordingly, I must determine whether the allegations in the Complaint establish violations of the Act.

Specifically, CTP alleges the following facts in its Complaint:

- Respondent owns Choice Tobacco, an establishment that sells tobacco products and is located at 603 Broadway East, Seattle, Washington 98102. Complaint ¶ 2.
- During an inspection of Respondent's establishment on September 27, 2013, at an unspecified time, an FDA-commissioned inspector observed a staff person at Respondent's establishment sell "Blunt Wrap Sweet Berry cigarettes [.]" Complaint ¶ 11.
- On November 21, 2013, CTP issued a Warning Letter to Respondent regarding the inspector's observation from September 27, 2013. The letter explained that the observation constituted a violation of regulations found at 21 U.S.C. § 387g(a)(1)(A). The Warning Letter stated that if Respondent failed to correct the violations, regulatory action by the FDA or a civil money penalty action could occur and that Respondent was responsible for complying with the law. Complaint ¶ 11.
- Aswad Janoo, who identified himself as the establishment's owner, responded to the Warning Letter by a December 5, 2013 letter. "Mr. Janoo stated that all the 'Blunt Wrap Sweet Berry Cigarettes' were destroyed. He also stated that he had all his employees check the displays to ensure compliance." Mr. Janoo also informed CTP that he "implemented a new policy of monthly checks of the displays to prevent this violation in the future." Complaint ¶ 12.

• During a subsequent two-part inspection of Respondent's establishment conducted on February 18, 2014, and March 4, 2014, FDA-commissioned inspectors documented the sale of "Blunt Wrap Sweet Berry 100's," "Milds," and "Milds 100's" Premium Flavored Cigarettes in the Respondent's establishment. Complaint¶ 1.

These facts establish that Respondent is liable under the Act. The Act prohibits misbranding of a tobacco product. 21 U.S.C. § 331(k). A tobacco product is misbranded if distributed or offered for sale in any state in violation of regulations issued under section 906(d) of the Act. 21 U.S.C. § 387c(a)(7)(B); 21 C.F.R. § 1140.1(b). The Act also prohibits the receipt in interstate commerce of any tobacco product that is adulterated, and the delivery or proffered delivery thereof for pay or otherwise. 21 U.S.C. § 331(c). The Secretary of the U.S. Department of Health and Human Services issued the regulations at 21 C.F.R. pt. 1140 under section 906(d) of the Act. 21 U.S.C. § 387a-1; see 21 U.S.C. § 387f(d)(1); 75 Fed. Reg. 13,225, 13,229 (Mar. 19, 2010). The regulations prohibit a cigarette or any of its component parts (including the tobacco, filter, or paper) from containing, as a constituent (including a smoke constituent) or additive, an artificial or natural flavor (other than tobacco or menthol) or an herb or spice that is a characterizing flavor of the tobacco product or tobacco smoke. 21 U.S.C. § 387g(a)(1)(A).

Taking the above alleged facts as true, Respondent violated the prohibition against selling cigarettes that contain a constituent, additive, artificial, natural flavor, herb or spice as a characterizing flavor of the tobacco product or tobacco smoke. 21 U.S.C. § 387g(a)(1)(A), on September 27, 2013, February 18, 2014, and March 4, 2014.

CTP has requested a civil fine of \$500, which is a permissible fine under the regulations. 21 C.F.R. § 17.2. Therefore, I find that a civil penalty of \$500 is warranted and so order one imposed.

Steven T. Kessel

Administrative Law Judge